or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976, e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

[54 FR 25043, June 12, 1989]

Subpart B—Biological Stains

§ 864.1850 Dye and chemical solution stains.

(a) *Identification.* Dye and chemical solution stains for medical purposes are mixtures of synthetic or natural dyes or nondye chemicals in solutions used in staining cells and tissues for diagnostic histopathology, cytopathology, or hematology.

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807. The devices are also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 60583, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

Subpart C—Cell And Tissue Culture Products

§ 864.2220 Synthetic cell and tissue culture media and components.

(a) *Identification.* Synthetic cell and tissue culture media and components are substances that are composed entirely of defined components (e.g., amino acids, vitamins, inorganic salts, etc.) that are essential for the survival and development of cell lines of humans and other animals.

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60583, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.2240 Cell and tissue culture supplies and equipment.

(a) *Identification.* Cell and tissue culture supplies and equipment are devices that are used to examine, propagate, nourish, or grow cells and tissue cultures. These include such articles as slide culture chambers, perfusion and roller apparatus, cell culture suspension systems, and tissue culture flasks, disks, tubes, and roller bottles.

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter. If the devices are not labeled or otherwise represented as sterile, they are exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

[45 FR 60584, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§ 864.2260 Chromosome culture kit.

(a) *Identification.* A chromosome culture kit is a device containing the necessary ingredients (e.g., Minimum Essential Media (MEM) of McCoy's 5A culture media, phytohemagglutinin,

fetal calf serum, antibiotics, and heparin) used to culture tissues for diagnosis of congenital chromosome abnormalities.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60585, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§864.2280 Cultured animal and human cells.

(a) *Identification.* Cultured animal and human cells are in vitro cultivated cell lines from the tissue of humans or other animals which are used in various diagnostic procedures, particularly diagnostic virology and cytogenetic studies.

(b) *Classification.* Class I (general controls).

[45 FR 60585, Sept. 12, 1980]

§864.2360 Mycoplasma detection media and components.

(a) *Identification.* Mycoplasma detection media and components are used to detect and isolate mycoplasma pleuropneumonia-like organisms (PPLO), a common microbial contaminant in cell cultures.

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60586, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§864.2800 Animal and human sera.

(a) *Identification.* Animal and human sera are biological products, obtained from the blood of humans or other animals, that provide the necessary growth-promoting nutrients in a cell culture system.

(b) *Classification.* Class I. The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60586, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§864.2875 Balanced salt solutions or formulations.

(a) *Identification.* A balanced salt solution or formulation is a defined mixture of salts and glucose in a simple medium. This device is included as a necessary component of most cell culture systems. This media component controls for pH, osmotic pressure, energy source, and inorganic ions.

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 60586, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

Subpart D—Pathology Instrumentation and Accessories

§864.3010 Tissue processing equipment.

(a) *Identification.* Tissue processing equipment consists of devices used to prepare human tissue specimens for diagnostic histological examination by processing specimens through the various stages of decalcifying, infiltrating, sectioning, and mounting on microscope slides.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

[45 FR 60587, Sept. 12, 1980, as amended at 54 FR 25044, June 12, 1989]

§864.3250 Specimen transport and storage container.

(a) *Identification.* A specimen transport and storage container, which may be empty or prefilled, is a device intended to contain biological specimens, body waste, or body exudate during storage and transport in order that the matter contained therein can be destroyed or used effectively for diagnostic examination. If prefilled, the device contains a fixative solution or other general purpose reagent to preserve the condition of a biological specimen added to the container.

(b) *Classification.* Class I (general controls). If the device is not intended for over-the-counter (OTC) distribution, it